Eurogentec

GMP Biomanufacturing

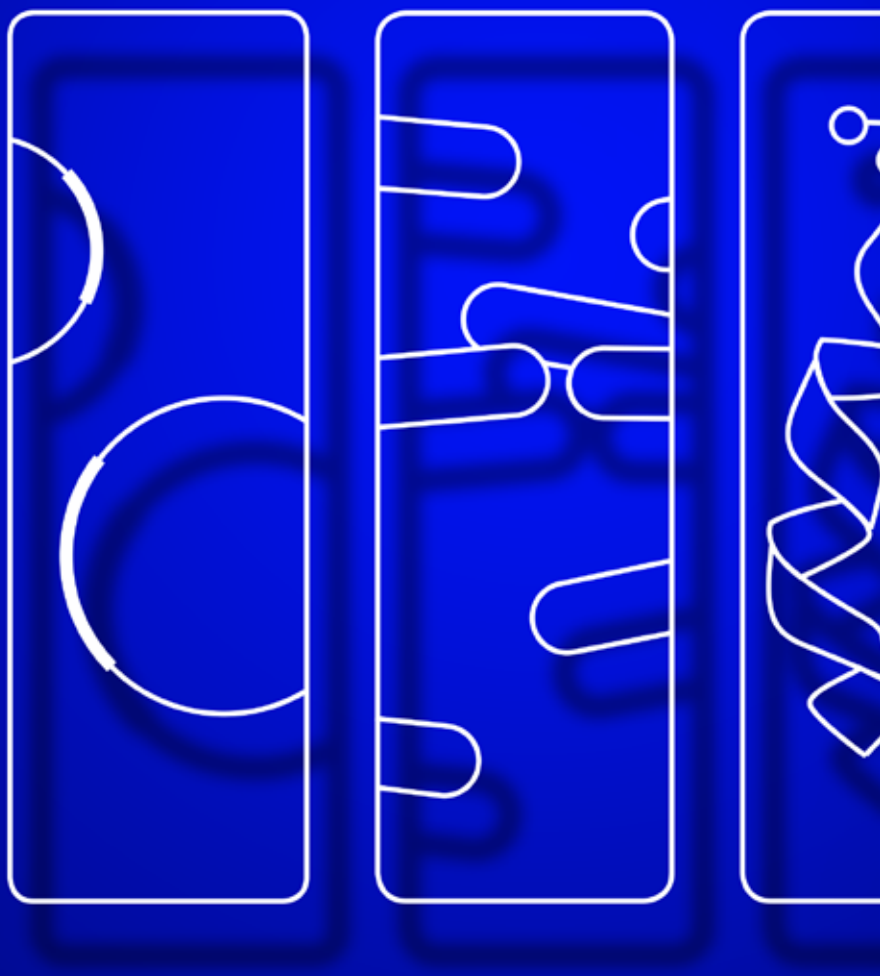
Proteins, Plasmids DNA, IVT-RNA, Conjugates

> Microbial experts

> Clinical and commercial manufacturing

> FDA inspected 2011, 2013, 2014, 2017

> GMP accredited since 1994



GMP
Recombinant proteins
Plasmid DNA
Protein conjugation
IVT-RNA

GMP Contract Manufacturing

Eurogentec is a GMP accredited manufacturer of parenteral biologics. We produce clinical trial material for all major markets according to FDA and EMA requirements. As experts in the manufacturing of biologics from bacterial and yeast sources, we offer significant know-how in high cell density fermentation, purification by refolding of inclusion bodies, isolation of periplasmic or extracellular secreted proteins, purification of intracellular soluble proteins as well as production of plasmid DNA, IVT-RNA and protein conjugates.

CLINICAL TRIAL AND COMMERCIAL BIOLOGICS MATERIAL

COMPREHENSIVE GMP EXPERIENCE

- GMP accredited since 1994
- FDA inspected 2011, 2013, 2014, 2017
- > 160 custom GMP processes developed, > 500 GMP batches released
- Manufacturing to FDA 21 CFR Part 210 & 211, EU 2003/94/EC and Eudralex Vol 4

EXPERIENCE IN ALL CLINICAL PHASES

- Manufacturing for Phase I, II, III and commercial
- Process development: USP, DSP, QC, preformulation
- QC qualification and validation plan
- Process characterization
- Process validation
- In-house QP release of DS and DP

PRODUCT EXPERIENCE

- Recombinant proteins (eg enzymes, cytokines, antibody fragments, fusion proteins)
- Plasmid DNA, API and starting material
- PEGylated proteins
- Peptide-protein conjugates

UNIQUE MANUFACTURING PLATFORMS

- Strain specific high density fed-batch fermentation methods
- Continuous / non-batch based purification methods, highly scalable
- Off-patent *Pichia pastoris* systems
- Low O-glycosylation fermentation conditions for *Pichia pastoris*
- Plasmid manufacturing to Kg scale
- IVT-RNA manufacturing

COMPREHENSIVE SERVICE OFFERING

- Cell line development *(E.coli* and *P.pastoris)*
- GMP Cell banking
- USP, DSP and QC development
- Stress stability studies
- Preformulation development
- API Manufacturing
- Fill & Finish, Packaging, Labeling
- Tox batch manufacturing
- GMP Clinical trial manufacturing
- Process characterization & validation
- GMP Commercial manufacturing
- ICH Stability studies on drug substance and drug product

GMP

Recombinant proteins
Plasmid DNA
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IVT-RNA

HOST SYSTEM EXPERIENCE

Manufacturing with all the important microbial strains

- *E. coli*
- *P. pastoris*
- *H. polymorpha*
- *S. cerevisiae*
- Biosafety level 2 aerobic micro-organisms that are non-sporulating

TECHNICAL EXPERTISE

- Fermentation development using a Design of Experiment approach with parallel 6x5 L fermentors
- Purification development by parallel screening of resins for multiple process performance properties
- In-house development of QC tests, IPC & release tests incl cell based potency assays
- Formulation by Design of Experiment based Stress stability studies
- Scale-down model validation
- Statistical approach to process analysis and specification setting

COMPREHENSIVE EXPRESSION EXPERIENCE

- Refolding of inclusion bodies
- Periplasmic expression
- Soluble cytoplasmic expression
- Extracellular secretion

MULTI-PRODUCT MANUFACTURING FACILITY

- 3 GMP Fermentation suites (up to 500L today, 2200L in 2020)
- 2 GMP Purification suites (additional suite in 2020)
- 1 GMP Sterile Filtration suite
- FDA inspected 2011, 2013, 2014, 2017

www.eurogentec.com

Biologics

For more information, please contact
biologics@eurogentec.com
http://biologics.eurogentec.com
tél.: +32 4 366 6116
fax: +32 4 365 1604

Kaneka Eurogentec S.A.
RPM Liège | TVA - (BE) - 0427-348-346
IBAN: BE70 5523 0418 0025
BIC: GKCCBEBB
Dexia Bank 552-3041800-25

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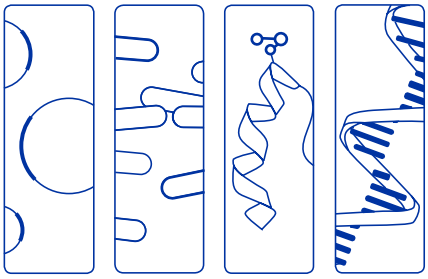

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Kaneka Eurogentec S.A. is part of Kaneka

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